

CHANGE OF PROTOCOL (COP)

Researchers may request approval to make modification or amendments in various aspects of a study. **All changes must be approved by the IRB prior to implementation.**

Amendments include the following:

- changes in experimental design
- insertion of new information or correction of errors
- change in principal investigator
- change in number of subjects
- changes in population and/or inclusion/exclusion criteria
- change in study site(s).

CLARKSON COLLEGE - Institutional Review Board (IRB) CHANGE OF PROTOCOL REQUEST	
Instructions: Researchers may request approval to make modification or amendments in various aspects of a study. All changes must be approved by the IRB prior to implementation. Approval of amendment request is not guaranteed.	
SECTION I	
IRB#:	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College ID#:	
Phone Numbers: _____ (work)	_____ (cell/home)
Clarkson College Email: ¹	
Co-Investigator:	
Address:	
Clarkson College ID#:	
Phone Numbers: _____ (work)	_____ (cell/home)
Clarkson College Email:	

¹ Investigators outside the College should provide the email address issued by their institution.

1. Amendment Description (**Check all as appropriate**):

- Amendment to currently approved procedures on the application (for example; changes to General information section, data collection methods section, confidentiality section, subject recruitment section, risk and benefits section etc.,)
- Amendment to Recruitment materials
- Amendment to currently approved consent/Assent/Permission forms
- Amendment to Debriefing forms
- Amendment to Data collection tools
- Other:

2. List and describe the proposed changes to each document or sections on the application:

3. State the reasons for the proposed changes:

4. List and describe potential risks that may occur as a result of the proposed amendment(s):

5. **Did you attach amended material**, as applicable (Note: **highlight/Bold/Underline all changes**)?

Yes

(Office Use Only)

IRB #: **Level of Review:** ___ Exempt ___ Expedited ___ Full-Board

Approved: Y or N **Date Approved:**

IRB Signature:

SECTION IV

Printed Name of Principal Investigator

Date

Signature of Principal Investigator

Submit to IRB@clarksoncollege.edu or mail them to the College or to the address listed below.

Note: Changes in protocol must not be implemented prior to IRB approval.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019